MAR 1 9 2001

Attachment 3

510(k) SUMMARY

K-Jump's WristWatch Blood Pressure Monitor, Model KP-6120 (K002665)

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Daniel Tseng
K-Jump Health Co., Ltd.
No. 56 Wu Kung 5th Road
Wu Ku Industrial Park
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Taiwan
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-or-

Jonathan S. Kahan, Esq.
Hogan & Hartson L.L.P.
555 Thirteenth Street, N.W.
Washington, DC 20004-1109
Phone: (202) 637-5794
Facsimile: (202) 637-5910

Date Prepared: November 16, 2000

Name of Device and Name/Address of Sponsor

WristWatch Blood Pressure Monitor, Model KP-6120

K-Jump Health Co., Ltd.
No. 56 Wu Kung 5th Road
Wu Ku Industrial Park
Taipei Hsien
Taiwan
Phone: 011 886 2 22991378
Facsimile: 011 886 2 22991386
Contact Person: Daniel C. M. Tseng

Common or Usual Name Blood Pressure Monitor

Classification Name System, Measurement, Blood Pressure, Non-Invasive

Predicate Devices Rossmax International, Ltd. WristWatch Blood Pressure Monitor

Intended Use/ Indications for Use

The K-Jump WristWatch Blood Pressure Monitor, Model KP-6120 is intended to measure the systolic and diastolic blood pressure, and pulse rate (heart rate) by using an inflating cuff which is wrapped around the wrist. The device is indicated for use in adults.

Technological Characteristics

The WristWatch BPM is designed to measure the systolic and diastolic blood pressure, and pulse rate (heart rate) of an individual. The device consists of an inflatable cuff that is wrapped around the wrist and held in place with Velcro™, an LCD display, a semiconductor sensor, an internal air pump, a battery power source, and keys for operation.

Performance Data

K-Jump conducted electromagnetic compatibility testing in accordance with EN 60601-1-2 (1993); EN 55011 (1991), IEC 801-2 (1991); IEC 801-3. The device was found to comply with these standards.

In addition, the K-Jump BPM complies with EN-1060-1 and EN 1060-3.

The device complies with the AAMI/ANSI SP10A-1996 standard. "Electronic or Automated Sphygmomanometer."

K-Jump conducted a clinical trial in accordance with the ANSI/AAMI SP10A-1996 "Electronic or Automated Sphygmomanometer" standard. Eighty-nine patients had their blood pressure and heart rate tested with both an Ausculatory Mercurial Sphygmomanometer and the WristWatch BPM. The data show these devices are substantially equivalent.

Substantial Equivalence

The WristWatch BPM is substantially equivalent to the Rossmax International Ltd. Rossmax BPM Blood Pressure Monitor RM4000. The WristWatch BPM and its predicate device are both noninvasive blood pressure monitors that take readings from the wrist rather than the upper arm using the oscillometric method. The WristWatch BPM and RM4000 have the same intended use, principles of operation and virtually identical technological characteristics. With the exception of minor variations in pressure measurement ranges, minimum operational relative humidity, minimum storage temperature and memory capacity, the devices are technologically identical. These minor differences do not raise any new issues of safety or effectiveness because both devices comply with the AAMI/ANSI SP10A-1996 standard. "Electronic or Automated Sphygmomanometer." Thus, the WristWatch BPM is substantially equivalent to the Rossmax RM 4000.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 9 2001

Mr. Jonathan S. Kahan
K-Jump Health Co., Ltd.
Hogan & Hartson L.L.P.
555 Thirteen Street, N.W.
Washington, DC 20004

Re: K002665
Trade Name: Wristwatch BPM Blood Pressure Monitor, Model KP-6120
Regulatory Class: II (two)
Product Code: DXN
Dated: December 19, 2000
Received: December 19, 2000

Dear Mr. Kahan:

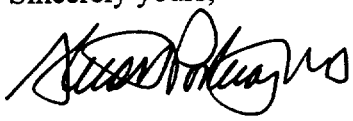
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): (K002665)

Device Name: **K-Jump Health Co., Ltd. WristWatch Blood Pressure Monitor, Model KP-6120**

Indications for Use:

The K-Jump WristWatch Blood Pressure Monitor, Model KP-6120 is intended to measure the systolic and diastolic blood pressure, and pulse rate (heart rate) by using an inflating cuff which is wrapped around the wrist. The device is indicated for use in adults.

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____
(Per 21 C.F.R. 801.109)

OR

Over-The-Counter Use ✓

(Optional Format 1-2-96)

3/19/1

Division of Cardiovascular & Respiratory Devices
510(k) Number K002665